

REMARKS

Applicants have carefully reviewed and considered the Office Action mailed on June 23, 2005 and the documents cited therewith.

No claims have been amended, added, or newly canceled; as a result, claims 1, 4, 7-22, and 25 are pending.

Rejection Under 35 U.S.C. § 102(b)

Claims 1, 4, 7, 13, 14, 20, 21, and 25 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by US Patent 6,060,085 to Osborne or US Patent 5,863,560 to Osborne, both previously of record, as evidenced by the newly cited Russell article (*American Family Physician* 2000, 61(2), 357-66). This rejection is respectfully traversed.

Initially, it should be noted that Osborne '085 is a continuation of Osborne '560. Therefore, the two disclosures are virtually identical. Accordingly, in order to simplify the arguments below, Applicant will refer only to Osborne, but the arguments apply to both Osborne '560 and Osborne '085.

The Examiner asserted that Osborne discloses Dapsone in a topical composition for treatment of acne. She has cited Russell as evidence that acne can be non-inflammatory, inflammatory, or a mixture of both, and that the most common situation is the mixture of both. The Examiner admitted that Osborne does not disclose treatment of non-inflammatory acne, but she asserted that nothing in Osborne indicates that the acne being treated is not the most common form (mixed non-inflammatory and inflammatory) and nothing in Osborne indicates that the acne being treated is only inflammatory acne. Therefore, the Examiner concluded that Applicant's method for reducing a number of non-inflammatory acne lesions and method for treating non-inflammatory acne is inherent in Osborne.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). To constitute anticipation, the claimed subject matter must be identically disclosed in the prior art. *In re Arkley*, 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). For anticipation, there must be no difference

between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

Moreover, an anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

The Examiner is incorrect that nothing in Osborne indicates that the acne being treated is not the most common form (mixed non-inflammatory and inflammatory) and nothing in Osborne indicates that the acne being treated is only inflammatory acne. Osborne defines acne in the Background of the Invention section as follows:

Acne is chronic pilosebaceous unit **inflammation** associated with the face and trunk usually occurring in adolescence due to complex interactions of androgens and bacteria. For the adolescent, circulating androgen results in significantly increased sebum production. The sebaceous glands dramatically enlarge and excrete more sebum than the immature pilosebaceous canals can accommodate. Simultaneously, anaerobic bacteria (*Propionibacterium acnes*) that feed upon the sebum, converting triglycerides to fatty acids, dramatically increase in number due to an increase in volume of the nutrition source. The increase in constricted immature ducts and bacterial waste products results in plugged follicles and **typical acne inflammation**.

Osborne at column 1 (emphasis added).

In addition, the Background of the Invention section discloses what is necessary to reduce the inflammation:

In order to reduce the amount of inflammation, the active pharmaceutical must penetrate past the stratum corneum and interfere with the cascade of inflammatory events. Ideally, delivery of an anti-inflammatory for acne requires that steady-state levels be sustained. To date, the ideal delivery system that provides antimicrobial agents above the stratum corneum while providing anti-inflammatory agents below the stratum corneum has not been implemented.

Osborne at column 2. Osborne then goes on to disclose in the sections that follow the Background of the Invention such an ideal delivery system that had not been implemented earlier.

Therefore, when Osborne is read in its entirety, it is clear from context that Osborne is treating only inflammatory acne. The Background of the Invention section cannot be ignored, and the other sections cannot be read isolated from the Background of the Invention. The definition of acne in the Background of the Invention section sets the stage for the compositions and methods for treating acne, which follow the Background of the Invention. When Osborne discloses, "a need exists for acne treatment that maximizes antimicrobial drug level in the upper third of the pilosebaceous unit", it is clear from context that he means acne as he defined it in the paragraph immediately preceding, namely inflammatory acne.

In fact, contrary to the assertions of the Examiner, nothing in Osborne would lead one to another interpretation for the definition of acne therein. Accordingly, reducing a number of non-inflammatory acne lesions or treatment of non-inflammatory acne cannot be said to flow as a necessary conclusion from the plain language of Osborne. As such, there is no inherency.

Withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claims 8-12 and 15-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent 6,060,085 to Osborne in view of Russell and US Patent 6,200,964 to Singleton et al. or over US Patent 5,863,560 to Osborne in view of Russell and US Patent 6,200,964 to Singleton et al. This rejection is respectfully traversed.

Again, it should be noted that Osborne '085 is a continuation of Osborne '560. Therefore, the two disclosures and the two rejections are virtually identical. Accordingly, in order to simplify the arguments below, Applicant will refer only to Osborne, but the arguments apply to both Osborne '560 and Osborne '085.

The Examiner recognizes that Osborne does not disclose cream, lotion, spray, suspension, or ointment formulations. In order to overcome this deficiency, she has cited Russell and Singleton et al. Furthermore, she has implicitly carried over her inherency argument from the § 102(b) rejection, *supra*.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation either in the cited references themselves or in the knowledge generally available to an art worker, to modify the reference or to combine reference teachings so as to arrive at the claimed method. Second, the art must provide a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations (M.P.E.P. § 2143). The teaching or suggestion to arrive at the claimed method and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure (M.P.E.P. § 2143 citing with favor, *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

Applicant reiterates his argument above that nothing in Osborne would lead one to include mixed non-inflammatory and inflammatory acne within Osborne's definition of acne. The citation of Russell and Singleton et al. does not overcome this deficiency. Accordingly, all of the claim elements are not disclosed by the cited documents alone or in combination because the documents do not disclose reducing a number of non-inflammatory acne lesions or treatment of non-inflammatory acne with Dapsone.

Moreover, a person of skill would know that other remedies, and not anti-microbials (such as Dapsone, disclosed in Osborne), are useful for the treatment of blackheads (i.e. non-inflammatory acne). Accordingly, the routineer would have had no motivation to use the combined disclosures for treating non-inflammatory acne or for reducing a number of non-inflammatory lesions. Nor would the routineer have had an expectation of success in using the combined disclosures for treating non-inflammatory acne or for reducing a number of non-inflammatory lesions. Such motivation and expectation of success come only from Applicant's disclosure. Therefore, the Examiner has not established a *prima facie* case of obviousness. Withdrawal of this rejection is respectfully requested.

RESPONSE UNDER 37 CFR § 1.111

Serial Number: 10/081,050

Filing Date: February 20, 2002

Title: Topical Dapsone for the Treatment of Acne

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CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at 703-239-9592 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

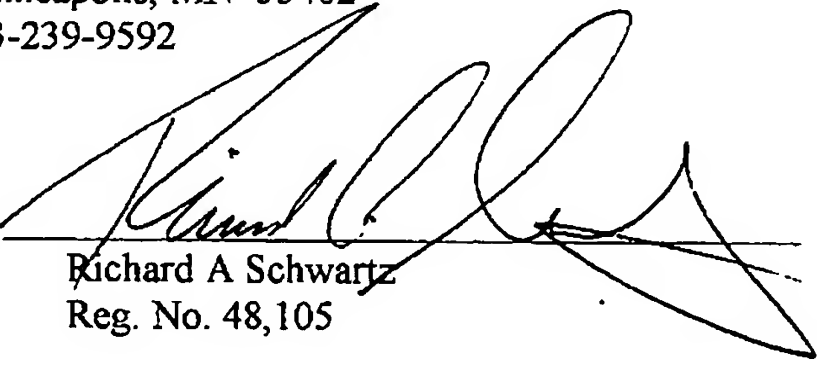
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Date 23RD September 2005

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23rd day of September, 2005.

Name

Signature